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UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
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OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

Dear Mr. Wilson:

The attached application for patent term extension of U.S. Patent No. 4,724,231 was filed on January 3, 1997, under 35 U.S.C. § 156. U.S. Patent No. 4,724,231 issued on February 9, 1988, from an application that claimed priority under 35 U.S.C. § 120 to an application that was filed on April 16, 1985. Accordingly, the original expiration date of the patent is April 16, 2005. 35 U.S.C. § 154.

The assistance of your Office is requested in confirming that the product identified in the application, NASOBAL™ (cyanocobalamin; Vitamin B₁₂), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would NOT be eligible for extension of the patent term under 35 U.S.C. § 156 if regulatory review for NASOBAL™ occurred only under § 505 of the FDCA and the active ingredient, cyanocobalamin; Vitamin B₁₂, was previously approved under § 505 of the FDCA and is the only active ingredient of NASOBAL™. In re Alcon Laboratories, 13 USPQ2d 1115 (Comm'r. Pats. 1989).

Telephone inquiries regarding this communication should be directed to the undersigned at (703) 306-3159.

Karin Tyson
Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Project

cc: Gerald T. Bodner, Esq.
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WASHINGTON, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
06/848690	04/08/86	WENIG	17864A

HENRY T. BURKE
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EXAMINER
ROBINSON, DOUGLAS

ART UNIT	PAPER NUMBER
1205	15

DATE MAILED: 06/09/97

This is a communication from
the Patent & Trademark Office

PATENT NUMBER: 4724231

This is in response to the Power of Attorney filed 12/02/96

- () 1. The Power of Attorney to you in this application **has been revoked** by the applicant. Future correspondence will be mailed to the new address of record. 37 CFR 1.33.
- ☒ 2. The Power of Attorney to you in this application **has been revoked** by the assignee who has intervened as provided by 37 CFR 3.71. Future correspondence will be mailed to the new address of record. (37 CFR 1.33).
- () 3. The withdrawal as attorney in this application **has been accepted**. Future correspondence will be mailed to the new address of record. 37 CFR 1.33.
- ☒ 4. The Power of Attorney in this application **is accepted**. Correspondence in this application will be mailed to the below-noted address as provided by 37 CFR 1.33.
- () 5. The Power of Attorney in this application **is not accepted** for the reason(s) checked below:
- () a. The Power of Attorney is from an assignee and the Certificate required by 37 CFR 3.73(b) has not been received.
- () b. The person signing for the assignee has omitted their empowerment to sign on behalf of the assignee.
- () c. The inventor(s) is without authority to appoint attorneys since the assignee has intervened as provided by 37 CFR 3.71.
- () d. The signature of _____, a co-inventor in this application, has been omitted. The Power of Attorney will be entered upon receipt of confirmation signed by said co-inventor.
- () e. The person(s) appointed in the Power of Attorney is not registered to practice before the U.S. Patent & Trademark Office.
- () f. The revocation is not signed by the applicant, the assignee of the entire interest, or one particular principal attorney having the authority to revoke.

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